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| EXAMINER | |
|---|---|
| WANG, ANDREW J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1639 | |

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/416,902 | MCCAFFERTY ET AL. | |
| | Examiner | Art Unit | |
| | Padmashri Ponnaluri | 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *44,47,48 and 53-62* is/are pending in the application.

4a) Of the above claim(s) *53-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44,47,48,61 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/971,857.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. The amendment and the response filed on 11/30/05 has been fully considered and entered into the application.

2. Applicant's election of group I, claims 44-52 in the reply filed on 3/15/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 53-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/15/04.

4. New claims 61-62 have been added and claims 46, 51-52, have been canceled by the amendment filed on 11/30/05.

5. Claims 44, 47-48, 53-62 are currently pending; claims 53-60 are withdrawn and claims 44, 47-48, and 61-62 are currently being examined in this application.

### *Priority*

6. This application is a divisional of 08/484,893, which is continuation of 07/971,857, which is a continuation of PCT/GB91/01134.

7. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 07/971,857, filed on 1/8/93.

***Withdrawn Claim Rejections***

8. The obviousness-type double patenting rejection of claims 44, 46-48 and 51-52 over claims 1-59 of U.S. Patent No. 5,969,108, has been withdrawn in view of the terminal disclaimer filed on 11/30/05.

9. The provisional obviousness-type double patenting rejection of claims 44, 46-48 and 51-52, over claims 1-5 of copending Application No. 10/803,653 has been withdrawn in view of the terminal disclaimer filed on 11/30/05.

10. The provisional obviousness-type double patenting rejection of claims 44, 46-48 and 51-52, over claims 1-17 of copending Application No. 10/803,622 has been withdrawn in view of the terminal disclaimer filed on 11/30/05.

***Maintained Claim Rejections***

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. The rejection of claims 44, 47-48 under 35 U.S.C. 102(e) as being anticipated by US Patent 5,837,500 (Ladner et al) (filing date 9/2/1998) has been maintained for the reasons set forth in the previous office action mailed on 7/28/05.

13. The rejection of claims 44, 46-48, (canceled claims 51-52) and new claims 61-62 under 35 U.S.C. 102(a or e) as being anticipated by US 2002/0150881 A1 (Ladner et al) (effective filing date 9/2/1988) has been maintained for the reasons set forth in the previous office action mailed on 7/28/05.

14. The rejection of claims 44, 47-48 under 35 U.S.C. 102(e) as being anticipated by US Patent 5,427,908 (Dower et al) (filing date 5/1/1990) has been maintained for the reasons set forth in the previous office action mailed on 7/28/05.

***New Claim Rejections Necessitated by the Amendment***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 44, 47-48 are rejected under 35 U.S.C. 102(e, a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dower (US Patent 5,427,908).

The instant claims briefly recite a method of obtaining a member of specific binding pair, by contacting a library of filamentous bacteriophage particles displaying a population of specific binding pair members, which comprise Fab antibody fragments, with a desired epitope (target).

The limitation "providing a library of in vitro mutagenized nucleic acid from an existing antibody coding sequence" is still considered as product-by-process limitation" is considered as 'product-by-process' limitation.

Dower et al teach filamentous bacteriophage library encoding antibody fragments (refers to the instant claim binding domains of immunoglobulin). The reference teaches that the bacteriophage library is screened for antibody fragments which bind specifically to a ligand of interest (refers to the desired epitope of the instant claims). The reference teaches that the bacteriophage particle encoding the antibody fragment that binds specifically to the antigen is selected (i.e., see claim 1), and the bacteriophage particles are enriched by repeating the selection step. Dower et al teach that the nucleic acid encoding the antibody fragment is isolated (refers to the instant claim 48) (i.e., see claim 8). The reference further teaches that the library is constructed by cloning the cDNA from the donor cells (i.e., see column 8). The reference further teaches that the phage particles displaying the specific antibody fragment are propagated, and the phage is harvested and DNA prepared and sequences to determine the DNA and amino acid sequence (refers to the instant claims 47-48) (i.e., see column 12).

Dower teaches that when the desired protein is an antibody, RNA or cDNA may be prepared from the spleen cells from animals immunized with antigen or hapten of interest ,

which reads on the library of nucleic acids of the instant claims. Dower further teaches that the desired protein is an immunoglobulin, a library expressing antibody light chain regions may be combined with one expressing antibody heavy chain binding regions, thereby constructing combinatorial antibody or Fab expression libraries (see i.e., column 4).

The claimed invention differs from the prior art teachings by reciting that the library of nucleic acid is obtained by in vitro mutagenized nucleic acid from an existing antibody coding regions. Dower teaches that when the desired protein is an antibody, RNA or cDNA may be prepared from the spleen cells from animals immunized with antigen or hapten of interest. Dower does not teach that the library is prepared by in vitro mutagenized nucleic acid from existing antibody coding sequences, however, the limitation is considered as product-by-process limitation. The library of nucleic acid used in the instant claimed method appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific source of the library of nucleic acids of the instant versus the reference library of nucleic acid sequences. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed library (is structurally or functionally) is different from the one taught by prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 U. S. P. Q. 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

*"The instant claims are written as product-by-process claims. "Even though the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability is based on the product itself. The patentability of a*

*product does hot depend on its method of production. If the product in the product-by-process claims is same or as obvious from the product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." In re Thorpe, 777 F. 2d 695, 698, 227 U. S. P. Q. 964, 966 (Fed. Cir. 1985). (see MPEP 2113).*

***Response to Arguments***

19. *Claims 44, 47-48 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,837,500 (Ladner et al) (filing date 9/2/1998).*

*The instant claims briefly recite a method of obtaining a member of specific binding pair, by contacting a library of filamentous bacteriophage particles displaying a population of specific binding pair members, which comprise a binding domain of an immunoglobulin, with a desired epitope (target).*

*The limitation 'wherein the nucleic acid in the library is provided by in vitro mutagenesis of an existing antibody coding sequence or pre-existing phage antibodies' is considered as 'product-by-process' limitation.*

*Ladner et al disclose a method of obtaining a nucleic acid encoding a proteinaceous binding domain (refers to the member of specific binding pair of the instant claims) that binds a predetermined target (refers to the desired epitope of the instant claims) (i.e., see claim 1). Ladner further discloses that method comprises a) providing a variegated population of filamentous phage (refers to the instant claim library of filamentous bacteriophage), each phage providing a nucleic acid construct coding for a chimeric potential binding protein, each*

*construct comprising DNA encoding a mutant of antibody domain(i.e., see claims 1, 4) ( refers to the instant claim binding domain of immunoglobulin); b) expressing the potential proteins and displaying said potential binding domains on the outer surface of said phage; c) contacting said phage with the predetermined target material such that potential binding domains and the target may interact; d) separating the phage displaying a potential binding domain; e) recovering the phage (refers to the instant claim method steps) (i.e., see claim 1), and amplifying said binding domain encoding nucleic acids in vivo or in vitro (refers to the instant claim 48). Ladner discloses that the binding domains are antibody domains (refers to 'the binding domain of immunoglobulin' of the instant claims), and further teach that the population of the filamentous phage is obtained by subcloning a mixture of DNA encoding a plurality of different chimeric proteins comprising different potential binding domains. Ladner discloses a method to produce the target binding protein variants (refers to the instant claim 47). Thus, the reference clearly anticipates the claimed invention.*

20. Applicant's arguments filed on 11/30/05, regarding the rejection of claims over Ladner (US Patent 5,837,500), have been fully considered but they are not persuasive.

Applicants traverse the rejection. Applicants argue that the amended claim 44 recites positive step of 'providing a library of in vitro mutagenized nucleic acid from an existing antibody coding sequence."

Applicant's arguments have been considered and are not persuasive for the following reasons. Initially, examiner like to point out that the newly added limitation "providing a library

of in vitro mutagenized nucleic acid from an existing antibody coding sequence" is still considered as product-by-process limitation.

Applicant's arguments have been fully considered and are not persuasive, since Ladner clearly teaches that the 'binding domain' is a mutant is a predetermined parental binding domain; and the parental binding domain is antibody; and further discloses that variegation of codons corresponding to the hypervariable region of antibody variable domain, which refer to the mutagenized nucleic acid from an existing antibody of the instant claims.

Applicants further argue that claim 44 is amended to recite that the specific binding pair member is a Fab antibody fragments.

Applicants traverse the rejection and argue that examiner's assertions are error. Applicants argue that Ladner does not disclose display on a filamentous bacteriophage multi-chain protein such as Fab antibody fragment.

Applicants arguments and assertions have been fully considered and are not persuasive, since Ladner (US Patent 5,837,500) claims are drawn to method of obtaining nucleic acid encoding a proteinaceous binding domain and display of the binding domain on a filamentous phage (see claim 1) ; claim 1 of the reference further recites; potential binding domain which is mutant of a predetermined parental binding domain (refers to the instant claim 'in vitro mutagenized nucleic acid); and claim 4 recites that the parental binding domain is an antibody domain ( refers to the instant claim antibody or fragment of antibody). Further Ladner discloses that antibody, Fab and fragments of Fab, and further discloses variegation of codons corresponding to the hypervariable region of antibody variable domain (refers to the Fab) (i.e., see column 15). Thus, Ladner clearly teaches all the limitations of the instant claims.

Further, applicants argue that Ladner teaches that its binding domain is preferably small (under 40 residues), while the instantly claimed Fab fragment is about 400 amino acids.

Applicants arguments are not persuasive, since the instant claim recites 'specific binding pair members are Fab antibody fragments', which may read on the small fragments (under 40 amino acids) taught by Ladner. Further, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., instantly claimed Fab fragment is about 400 amino acids long) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Thus for the reasons of record the rejections have been maintained.

21. *Claims 44, 46-48, 51-52 are rejected under 35 U.S.C. 102(a or e) as being anticipated by US 2002/0150881 A1 (Ladner et al) (effective filing date 9/2/1988).*

*The instant claims briefly recite a method of obtaining a member of specific binding pair, by contacting a library of filamentous bacteriophage particles displaying a population of specific binding pair members, which comprise a binding domain of an immunoglobulin, with a desired epitope (target).*

*The limitation 'wherein the nucleic acid in the library is provided by in vitro mutagenesis of an existing antibody coding sequence or pre-existing phage antibodies' is considered as 'product-by-process' limitation.*

*Ladner et al disclose a method of obtaining a nucleic acid encoding a proteinaceous binding domain (refers to the member of specific binding pair of the instant claims) that binds a predetermined target (refers to the desired epitope of the instant claims) (i.e., see claim 1). Ladner further discloses that method comprises a) providing a variegated population of filamentous phage (refers to the instant claim library of filamentous bacteriophage), each phage providing a nucleic acid construct coding for a chimeric potential binding protein; b) expressing the potential proteins and displaying said potential binding domains on the outer surface of said phage; c) contacting said phage with the predetermined target material such that potential binding domains and the target may interact; d) separating the phage displaying a potential binding domain; e) recovering the phage (refers to the instant claim method steps) (i.e., see claim 1), and amplifying said binding domain encoding nucleic acids in vivo or in vitro (refers to the instant claims 48, 52). Ladner discloses that the binding domains are antibody variable domains (refers to 'the binding domain of immunoglobulin' of the instant claims), and one more residues correspond to residues in the hypervariable region of said domains (i.e., see claims 4-5). Ladner et al teach that the population of the filamentous phage is obtained by subcloning a mixture of DNA encoding a plurality of different chimeric proteins comprising different potential binding domains. Ladner discloses a method to produce the target binding protein variants (refers to the instant claims 47, 51 method)(i.e., see claim 10). The 'antibody variable domains' of the reference claims read on the instant claim 'single chain antibodies or scFV,' because the reference teaches that 'the single chain antibody is a single chain polypeptide comprising two antigen binding regions to fold together to bind an antigen, .....and the two antigen binding regions must be variable domains of known antibody.' Thus, the reference claim variable*

*domains of an antibody read on the scFv of the instant claims. Thus, the reference clearly anticipates the claimed invention.*

*22.* Applicant's arguments filed on 11/30/05, regarding the rejection of claims over US 20020150881 (Ladner, now issued as US Patent 6,979,538) have been fully considered but they are not persuasive.

Applicants argue that the amended claim 44 recites positive step of 'providing a library of in vitro mutagenized nucleic acid from an existing antibody coding sequence."

Applicant's arguments have been considered and are not persuasive for the following reasons. Initially, examiner like to point out that the newly added limitation "providing a library of in vitro mutagenized nucleic acid from an existing antibody coding sequence" is still considered as product-by-process limitation.

Applicant's arguments have been fully considered and are not persuasive, since Ladner clearly teaches that the 'binding domain' is a mutant is a predetermined parental binding domain; and the parental binding domain is antibody; and further discloses that variegation of codons corresponding to the hypervariable region of antibody variable domain, which refer to the mutagenized nucleic acid from an existing antibody of the instant claims.

Applicants arguments that 'Ladner does not disclose filamentous bacteriophage of any multichain polypeptides such as Fab antibody fragments' has been considered and Is not persuasive, because Ladner (the `538 patent) claims recite 'displaying chimeric potential binding proteins on the outer surface of a population of filamentous phage'; 'phage is an M13, fl or fd phage'; and the potential binding domain is an antibody variable domain (reads on Fab, or single

chain antibody or fragments of antibody). New claims 61-62 have been included in this rejection since these claims are identical to the canceled claims 51-52. Thus the reference clearly anticipates the claimed invention.

23. *Claims 44, 47-48 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,427,908 (Dower et al) (filing date 5/1/1990).*

*The instant claims briefly recite a method of obtaining a member of specific binding pair, by contacting a library of filamentous bacteriophage particles displaying a population of specific binding pair members, which comprise a binding domain of an immunoglobulin, with a desired epitope (target).*

*The limitation 'wherein the nucleic acid in the library is provided by in vitro mutagenesis of an existing antibody coding sequence or pre-existing phage antibodies' is considered as 'product-by-process' limitation.*

*Dower et al teach filamentous bacteriophage library encoding antibody fragments (refers to the instant claim binding domains of immunoglobulin). The reference teaches that the bacteriophage library is screened for antibody fragments which bind specifically to a ligand of interest (refers to the desired epitope of the instant claims). The reference teaches that the bacteriophage particle encoding the antibody fragment that binds specifically to the antigen is selected (i.e., see claim 1), and the bacteriophage particles are enriched by repeating the selection step. Dower et al teach that the nucleic acid encoding the antibody fragment is isolated (refers to the instant claim 48) (i.e., see claim 8). The reference further teaches that the library is constructed by cloning the cDNA from the donor cells (i.e., see column 8). The reference further*

*teaches that the phage particles displaying the specific antibody fragment are propagated, and the phage is harvested and DNA prepared and sequences to determine the DNA and amino acid sequence (refers to the instant claims 47-48) (i.e., see column 12). Thus, the reference clearly anticipates the claimed invention.*

24. Applicant's arguments filed on 11/30/05, regarding the rejection over Dower (US Patent 5,427,908) have been fully considered but they are not persuasive.

Applicants traverse the rejection, and argue that Dower do not teach the newly added limitation 'providing a library of in vitro mutagenized nucleic acid from an existing antibody coding sequence.'

Applicants arguments have been fully considered and are not persuasive. Initially, examiner like to point out that the newly added limitation "providing a library of in vitro mutagenized nucleic acid from an existing antibody coding sequence" is still considered as product-by-process limitation. The limitation is considered as the library of nucleic acid, which is in vitro, mutagenized antibody coding sequences.

Further, applicants arguments are not persuasive, because Dower teaches that when the desired protein is an antibody, RNA or cDNA may be prepared from the spleen cells from animals immunized with antigen or hapten of interest , which reads on the library of nucleic acids of the instant claims. Dower further teaches that the desired protein is an immunoglobulin, a library expressing antibody light chain regions may be combined with one expressing antibody heavy chain binding regions, thereby constructing combinatorial antibody or Fab expression

libraries. Thus, the reference clearly teaches all the limitations of the instant claims, and the rejection of record has been maintained.

***Conclusion***

25. No claims are allowed.

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

22 February 2006